FEB 27 2013

510(K) SUMMARY

INMODE HAIR REMOVAL (HR) DEVICE

510(k) Number K 123682

Applicant Name:

Company Name: InMode MD Ltd.
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Israel
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Contact Person:

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Date Prepared: November, 25, 2012

Trade Name: InMode Hair Removal (HR) Device

Classification Name: CFR Classification section 878.4810; (Product code GEX)

Classification: Class II Medical Device

Predicate Device:

The InMode Hair Removal (HR) device is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
Lumenis Ltd., formerly Star Medical/Coherent	LightSheer	K001746
Quantel Derma GmbH	Leda EPI 808	K090762

Device Description:

The InMode Hair Removal (HR) device is designed to deliver optical energy to the skin via a pre-cooled sapphire block. The good optical contact between sapphire block and skin is achieved by using water based gel. The device provides individual adjustment of light fluence and pulse duration to achieve maximum efficiency and safety for each patient. The scanning system embedded into the laser InMode HR hand piece allows efficient treatment with less risk of overlap. The hand piece has integrated skin cooling to enhance safety and comfort of the treatment.

The InMode Hair Removal device consists of an AC/DC power supply unit, a diode driver, water cooling system, controller and user interface including an LCD screen and functional buttons. The diode laser hand piece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece comprises the InMode HR laser with linear scanning system, cooled sapphire output window (8 x 50mm), and electronic shutter.

The sapphire light guide is located on the front tip of the hand piece and delivers the laser beam energy to the treated tissue, while cooling the skin. The pair of thermoelectric coolers (TECs) located on both sides of the sapphire block provide cooling to a temperature of 4°C. The hand piece contains a trigger button which starts the laser scan and radiation. Fluence (light energy density) is delivered within the limits of 10 to 60J/cm2. The hand piece has a cable that is 170cm long and connects to the hand piece to the console via a connector.

Intended Use/Indication for Use:

The InMode Hair Removal (HR) device is indicated for use for hair removal.

Performance Standards:

The InMode Hair Removal (HR) Device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60825-1 - Safety of laser products, Part 1: Equipment classification and requirements;
- IEC 60601-2-22 – Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;
- IEC 60601-1-4 Medical electrical equipment – Part 1-4:General requirements for safety – Collateral Standard: Programmable electrical medical systems

Non-Clinical Performance Data:

Additionally, bench tests were conducted comparing the InMode Hair Removal (HR) device laser output parameters to those of the Leda EPI 808 predicate device. The results of the bench test demonstrate that the InMode HR device has the same laser output specifications as the predicate Leda EPI 808 device and therefore, is substantially equivalent to the predicate device.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use of the InMode Hair Removal (HR) device are substantially equivalent to the indications for use of the LightSheer and the Leda EPI 808 predicate devices. The design and components in the InMode Hair Removal (HR) device, including the console (with power supply, software, cooling system and touch screen user interface), the water-cooled hand piece (with cable and connector to console) and the foot switch are similar to the design and components found in the LightSheer and Leda EPI 808 predicate devices. The performance specifications (including wavelength, fluence, pulse width, pulse repetition rate, spot size and cooling) in InMode Hair Removal (HR) device are similar to performance specifications in the LightSheer and Leda EPI 808 predicate devices. These safety features in the InMode Hair Removal (HR) device are substantially equivalent to the safety features found in the predicate devices. The performance tests demonstrated that any minor differences in the device software and specifications meet the system requirements and do not raise new safety or effectiveness concerns. Consequently, the InMode Hair Removal (HR) device is substantially equivalent to the LightSheer predicate device, cleared under 510(k) K001746, and to the Leda EPI 808 predicate device, cleared in 510(k) submission K090762, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode Hair Removal (HR) device is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Inmode Hair Removal (HR) Device
% A.Stein-Regulatory Affairs Consulting, Limited
Ahava Stein
Regulatory Manager
20 Hata'as Street, Suite 102
Kfar Saba, Israel 44425

February 27, 2013

Re: K123682
Trade/Device Name: InMode Hair Removal (HR)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 27, 2012
Received: November 30, 2012

Dear Ahava Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

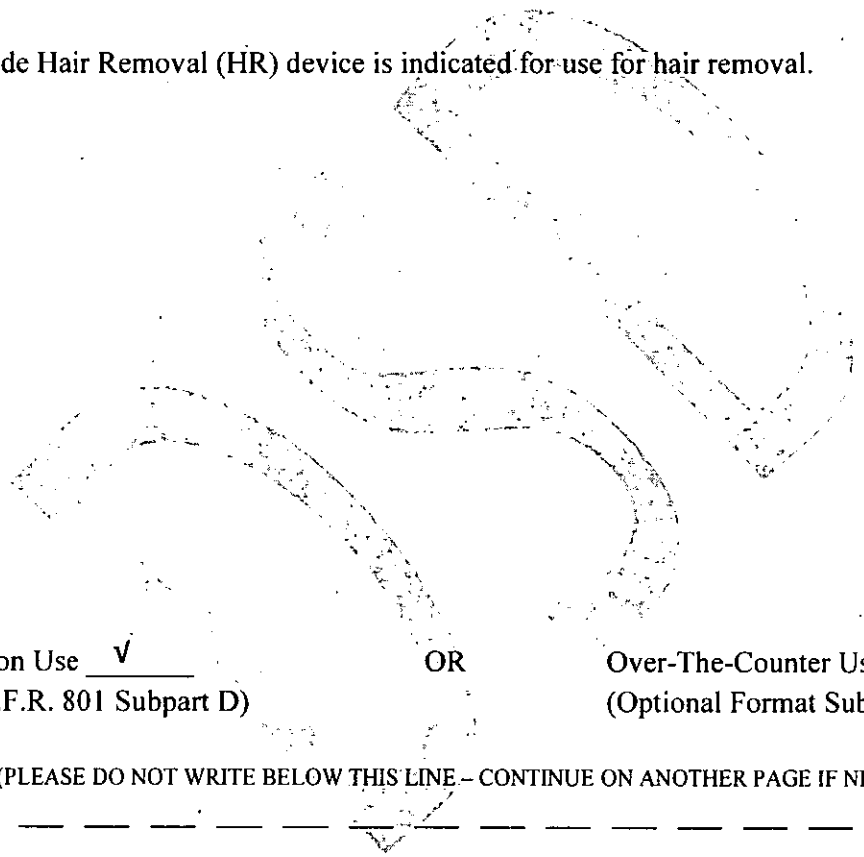
INDICATIONS FOR USE

510(k) Number (if known): K123682

Device Name: InMode Hair Removal (HR)

Intended Use Statement:

The InMode Hair Removal (HR) device is indicated for use for hair removal.



Prescription Use √ OR Over-The-Counter Use _____
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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Division of Surgical Devices
for MXM

510(k) Number K123682